

OCT 24 2001

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510(k) SUMMARY

**Invacare Corporation's
Model Xterra GT Power Wheelchair**

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared.

Invacare Corporation
One Invacare Way
PO Box 4028
Elyria, Ohio 44036
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Contact Person: Edward A. Kroll
Director, Regulatory Affairs

Date Prepared: August 27, 2001

Name of Device and Name/Address of Sponsor

Model Xterra GT Power Wheelchair

Invacare Corporation
One Invacare Way
Elyria, Ohio 44036-2028
Phone: (440) 329-6000
Facsimile: (440) 365-4558

Common or Usual Name

Power Wheelchair

Classification Name

Wheelchair, Powered

Predicate Devices

Invacare Corporations' Action Arrow Front Wheel Drive Power Wheelchairs (K991168 June 25, 1999) and Permobil's Chairman Front Wheel Drive Power Wheelchair (K960951, April 4, 1997).

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Intended Use

The intended use of the Invacare Model Xterra GT Power Wheelchair is to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair.

Technological Characteristics and Substantial Equivalence

A. Device Description

The Invacare Model Xterra GT power wheelchair is a battery powered, motor driven device with the intended function and use of providing mobility to those persons limited to a sitting position that have the capability of operating a power wheelchair. It is a rigid or "non- folding" type power wheelchair, with front wheel drive capability.

The wheelchair frame is of rigid or non-folding type design. The frame consists of a combination both 2" diameter and 1 1/4 " diameter x .109 wall, steel tubing. The frame is of one piece, welded construction.

The wheelchair is designed with front wheel, beam type suspension. That is, the front swivel casters are mounted to two separate front extension frame members, and are thus, independent of each other. Each extension frame member pivots independently about its' own axis. This allows the chair to better negotiate small obstacles such as curbs, or ramps, from a complete stop. The rear casters pivot as well, and also serve as wheelchair anti-tippers.

The Invacare Xterra GT wheelchair incorporates a direct, front wheel drive train, which includes two separate right angle gear motors. Because it is a direct drive system, there are no belts, pulleys, chains, sprockets or the like, to periodically adjust or maintain. Both gearboxes are sealed and maintenance free. The upholstery is fabricated from either U240 Nylon, or reinforced vinyl, depending upon the user's preference. Both of these materials meet California 116 and 117 and Boston Fire Department BFD-1 specifications for fire retardancy.

The Invacare Xterra GT wheelchair is powered by two 22NF 12 VDC batteries. Access to the batteries is gained from underneath the chair. The chairs will travel approximately 15 to 21 miles between charges, depending on use.

B. Substantial Equivalence

The Invacare Model Xterra GT Power Wheelchair is substantially equivalent to Invacare Corporations' Action Arrow (K991168, June 25, 1999) and Permobil's Chairman Front Wheel Drive Power Wheelchair (K960951, April 4, 1997).

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PERFORMANCE DATA

As required by FDA's July 26, 1995, draft publication entitled "Guidance Document for the Preparation of Premarket Notification [510(k)] Applications for Mechanical and Powered Wheelchairs, and Motorized Three- Wheeled Vehicles", the Invacare Xterra GT Power Wheelchair was tested in accordance with ISO EMC Draft Standard 7176-14 (Titled "Draft ISO EMC Group Proposal: Electromagnetic Compatibility Addition" And Dated April 3, 1995) for powered wheelchairs and motorized scooters. In all instances, the Invacare Xterra GT Power Wheelchair met the required performance criteria and functioned as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 24 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Edward A. Kroll
Director, Regulatory Affairs
Invacare Corporation
One Invacare Way
P.O. Box 4028
Elyria, Ohio 44036

Re: K012909

Trade/Device Name: Invacare ZX2 Power Wheelchair
Regulation Number: 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: II
Product Code: ITI
Dated: September 20, 2001
Received: September 24, 2001

Dear Mr. Kroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

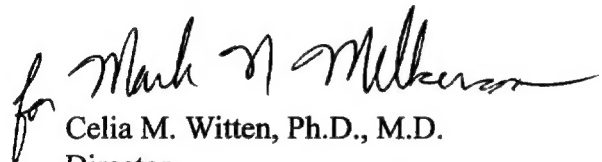
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Mark M. Milken

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): TBD K012909

Device Name: Invacare ZX2 Power Wheelchair

Indications For Use:

The intended use of the Invacare ZX2 Power Wheelchair is to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair.

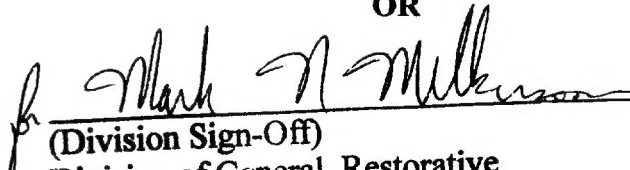
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(Optional Format 1-2-96)

510(k) Number K012909